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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,097	03/15/2004	Gustavo Antonio Moviglia	545872000100	4725

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EXAMINER	
QIAN, CELINE X	
ART UNIT	**PAPER NUMBER**
1636	
MAIL DATE	**DELIVERY MODE**
04/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,097	MOVIGLIA, GUSTAVO ANTONIO	
	Examiner	Art Unit	
	CELINE X. QIAN	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 24-77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0607*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-77 are pending in the application. Claims 1-9 and 24-77 are withdrawn from consideration. Claims 10-23 are currently under examination.

This Office Action is in response to the Amendment filed on 12/12/07.

Response to Amendment

The information disclosure statement (IDS) submitted on 7/23/07 has been considered by the examiner.

The rejection of claims 10-23 under 35 U.S.C.103(a) is maintained for reason set forth of the record mailed on 6/12/07 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo et al. (IDS, 1994), in view of Movglia (1996, IDS).

Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guo et al. (IDS, 1994), in view of Movglia (1996, IDS) and Gong et al (WO 01/59073).

In response to this rejection, Applicant argues that Guo reference only indicate that tumor hybrid cells (TBH) may provide a useful strategy for cancer immunotherapy. Further Applicant asserts that the method taught in Moviglia reference did not result in an effective therapy.

Applicant points to the specification and indicate that use of tumor/APC hybrids with either B cells or dendritic cells, does not provide sufficient immune response in cancer patients as demonstrated by the instant invention. The claimed invention is now loads dendritic cells outside of the body with tumor antigens using TBH to circumvent the tolerance. Applicant asserts that since TBH has not been proven to be effective tumor therapy, the inventor was forced to move on to a modified therapy, such that one of ordinary skill in the art would not be motivated to use Guo or Moviglia as a starting point to make the modifications asserted by the Examiner to be obvious. Applicant alleges that the examiner creates a reason for modifying Guo and Moviglia without citing any source for the asserted reason for modifying. Applicant argues that neither reference teaches that more CD8+ cells are needed, and since any procedure performs ex vivo carries the risk of introducing infection into a patient, one of skill in the art would look into other methods of increasing CD8+ response that minimizes ex vivo manipulations. Applicant argues since dendritic cells are recognized in the art to be the best at antigen presentation and priming CD4+ and CD8+ responses, one of ordinary skill in the art would choose dendritic cells as a better alternative as demonstrated by Tanaka et al., Gong et al., Homma et al., Wang et al., Celluzzi et al., Li et al. presented in IDS. Citing Gong et al. 2002, Celluzzi et al. 1998, and Wang et al. 1998, Applicant asserts that DCs are superior to B cells. Applicant thus asserts that all these references teach away from using any other antigen presenting cells, including inventor himself. Applicant further asserts that one of ordinary skill in the art would not have a reasonable expectation of success because a significant amount of time and effort is being devoted to working with tumor/DC hybrids to generate an effective

therapeutic system, and the claimed invention would have been unpredictable. Applicant asserts that the instant invention would not be obvious because one will not modify a failed system.

The above argument have been fully considered but deemed unpersuasive. The reason for obviousness of the claimed invention was set forth in the office action mailed on. There is no evidence provided by Applicant to prove that the art at the time of filing teaches away from using making a composition comprising TBH and CD8+ cells and to test its antitumor activity. The alleged failure of TBH to achieve clinical efficacy is irrelevant to the instant rejection because the claims are directed to a composition, not a method of therapy. While Applicant regards the invention is loading dendritic cells outside of body with tumor antigens using TBH to circumvent the tolerance, the claims do not reflect this invention because it is drawn to a composition that comprises TBH and CD8+ cells, and does not comprise any method steps of loading DC outside of body with TBH. In response to applicant's argument that there is no suggestion to combine the references, Applicant is reminded that the Supreme Court decision from KSR forecloses the argument that the motivation to combine the references needs to be taught in the reference itself. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the instant case, one of ordinary skill in the art would clearly recognize the importance of having more tumor specific CD8+ cells would be more effective to kill more tumor cells based on the teaching of both references because Guo et al. teach CD8+

cells mediate tumor specific cell destruction (see page 517, 2nd col., and Table 1, and page 518, 1st paragraph), and Moviglia teaches while antitumor effect of TBH in the induction period needs both CD4 and CD8 with sufficient number and competence, and only CD8 is necessary at the maintenance stage. Both references teach the involvement and importance of CD8+ cells, such that would lead an ordinary artisan to believe the number of CD8+ cells is important in mediate tumor specific killing. With regard to the argument of DC are better APC than TBH, the examiner finds the suggestion that the cited references teach away from the claimed composition is misconstrued. The cited section from Gong et al. 2002 merely states the function of DC being potent antigen presenting cells that initiate primary immune responses, and its difference from B lymphocytes and macrophages. The cited sections from Celluzi et al. and Wang et al. also comments on DC being the most effective APC. Since immunotherapy is an active area in cancer research while different approach may be explored, approaching the task using one type of approach does not exclude others approaches. As reflected in the specification [003]-[004], using tumor DC hybrid also has limitations. Contrary to Applicant's assertion, if a system has limitation, an ordinary skill in the art would be motivated to modify the system based on what is known in the art to improve it, not just turn away from it. Using DC as hybrid would be one of the improvement that can be made, which does not exclude other improvement such as stimulate CD8+ ex vivo with TBH. With regard to the unpredictability of success, Applicant is again reminded that the claims are directed to a product, which is obvious to make based on the cited references, not a method of achieving therapeutic effect, and the therapeutic effect of the claimed product is not part of the claim limitation. Based on the information known in the art, it is within an ordinary artisan's knowledge to understand the limitation of method using TBH, and DC

hybrids, and be motivated to try all possible options (not just one) to achieve the best result. Based on the teaching from Guo and Moviglia, it would have been obvious to an ordinary artisan to make a composition that comprises TBH and stimulated CD8+ cells, and he/she would have reasonable expectation of success to obtain such composition. Therefore, for reason discussed in the previous office action and above, this rejection is maintained.

Since Applicant does not provide a different reason for the rejection directed to claims 18-23, the rejection is maintained for same reason discussed in the previous office action and above.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian Ph.D./
Primary Examiner, Art Unit 1636